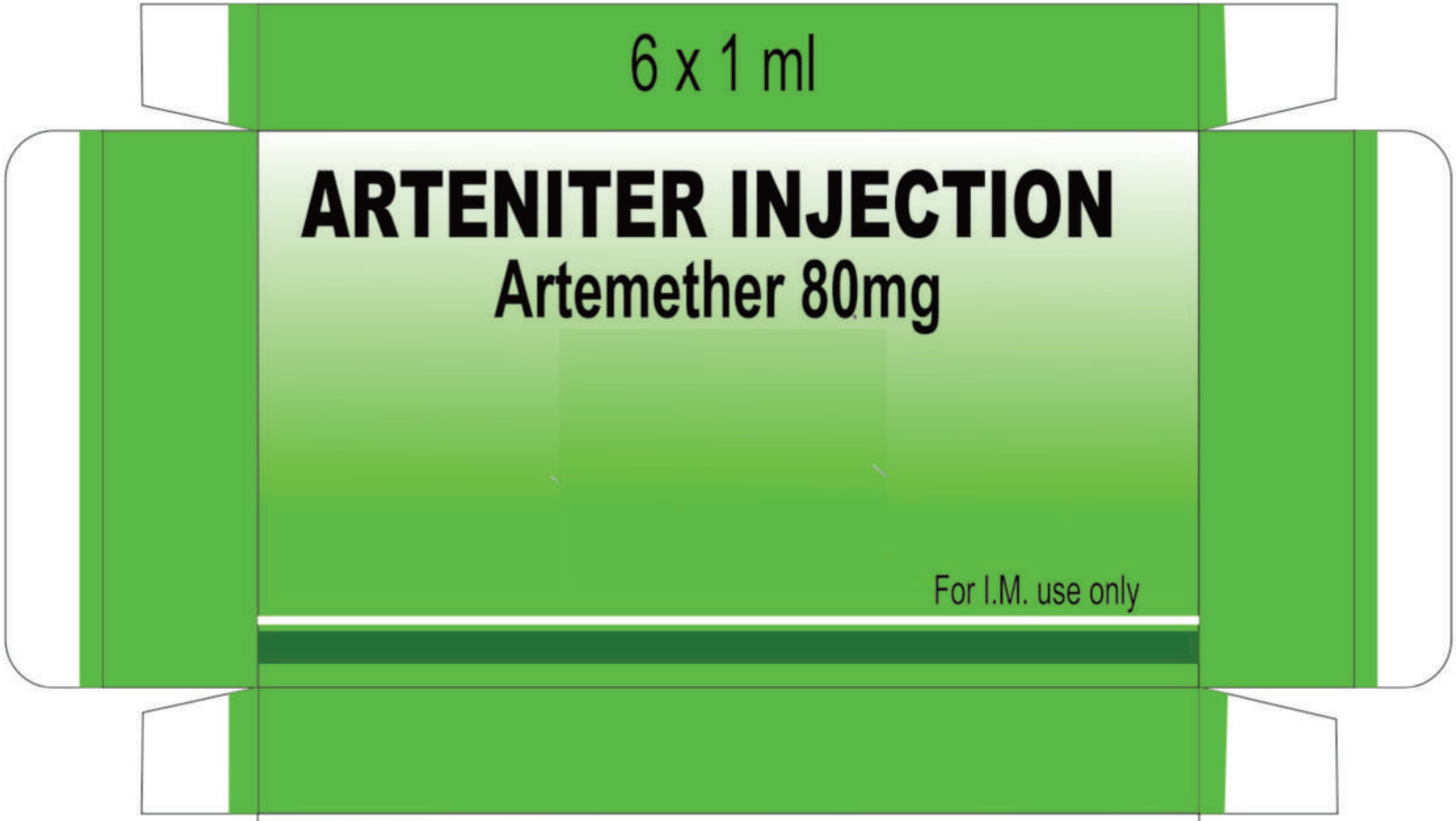

ARTENITER INJECTION
Artemether 80mg

Each ml contains
Artemether 80mg

Dosage: As directed by the Physician
Store below 30°C.

KEEP ALL MEDICINES OUT OF REACH OF CHILDREN.

Batch No.:
Mfg. Date:
Exp. Date:

NAFDAC REG. NO.: 04-9464

Manufactured By:
GREENFIELD PHARMA. (JIANG SU) CO., LTD.
No. 38, Tai Jiu Road, Tai Zhou,
Jiang Su Province, P.R. China.

Marketed By:
MAYDON PHARM & CHEM. CO., LTD.
15, Wilmer Street Off Town
Planning Way Ilupeju, Lagos.

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Artenither-80

Summary Product Characteristics (SPC)

1. Name of the medicinal product

Artenither-80

2. Qualitative and quantitative composition

Each ml contains 80mg artemether.

Excipient with known effect

Soybean oil is the excipient. There is 80mg artemether for unit dose of per ampoule, then add soybean oil to 1ml.

3. Pharmaceutical form

Injection.

Colorless to light yellow clear oil liquid

4. Clinical particulars

4.1 Therapeutic indications

In areas where multiple drug resistance exists, Artemether injection can be used to treat severe and complex malaria caused by Plasmodium falciparum in adults or children; And to treat malaria infected by the multidrug-resistant Plasmodium falciparum.

4.2 Posology and method of administration

Posology

The drug is used for intramuscular injection, five days course with the initial dose of 3.2mg/kg. followed by 1.6mg/kg for the following 4 days.

The initial dose for adults is 160mg, followed by 80mg every time from the 2^{nd} to 5^{th} day. The dose for children or overweight patients should be decreased or increased on the basis of the individual weight or under the doctor's prescription.

Administration for children: for children, the dose should be chosen as follows:

Age(year)	Weight	Total dose	Day 1	Day 2	Day 3	Day 4	Day 5
<1	<8kg	75mg	25mg	12.5mg	12.5mg	12.5mg	12.5mg
1-3	8-12.5kg	120mg	40mg	20mg	20mg	20mg	20mg
3-6	12.5-17.5kg	150mg	50mg	25mg	25mg	25mg	25mg
6-9	17.5-25kg	240mg	80mg	40mg	40mg	40mg	40mg
9-12	25-32kg	300mg	100mg	50mg	50mg	50mg	50mg
12-16	32-47kg	360mg	120mg	60mg	60mg	60mg	60mg

Method of administration

The drug is used for intramuscular injection.

For instructions on reconstitution of the medicinal product before administration, see section 6.6.

4.3 Contraindications

No.

4.4 Special warnings and precautions for use

Precautions

In cause of freeze due to coldness, please warm it before use.

Paediatric population

Effectiveness of Artemether injection in neonates, infants and children have been established for the dosages described under Posology and Method of Administration (see section 4.2).

4.5 Interaction with other medicinal products and other forms of interaction

Studies and reviews in the literature demonstrated that the active substance of Artemether had no interactions with other drugs on decreasing therapeutic effects and increasing toxicity and side effects in human bodies.

4.6 Fertility, pregnancy and lactation

Pregnancy

It should be used with caution in the first trimester of pregnancy since some fetus absorption has been observed.

Breastfeeding

Not applicable.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

Clinical dosage exhibits slight adverse reactions. A transient low fever and reticulocytopenia may occur in individual cases. Slight rise of SGOT and SGPT may occur in individual cases， Arrhythmia may occur in rare cases(such as ventricular tachycardia).

4.9 Overdose

Although no case of overdosage has been documented, in case of accident, symptomatic treatment is recommended under the instruction of doctors.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: antimalarials.

ATC code: P01BE02

Mechanism of action

Artemether is a derivative of artemisinin, which has a strong and rapid killing effect on the erythrocytic cycle of plasmodium, and can quickly control clinical seizures and symptoms. The mechanism of action of artemisinin is not yet fully understood, mainly by interfering with the surface membrane mitochondrial function of plasmodium. Artemisinin affects the ultrastructure of the erythrocytic cycle of plasmodium, causing changes in their membrane structure. Due to its effect on food vacuoles, it blocks the nutrient uptake of plasmodium. When plasmodium lose a large amount of cytoplasm and nutrients without being replenished, they quickly die. Its mode of action is mediated by the free iron produced by the decomposition of hemoglobin through its internal peroxide (dioxygen) bridge, producing unstable organic free radicals and/or other electrophilic mediators, and then forming covalent adducts with the proteins of plasmodium, causing their death. The antimalarial activity of artemether is six times greater than that of artemisinin.

5.2 Pharmacokinetic properties

The drug is absorbed rapidly and completely after i m. injection. The maximum blood concentration of the drug is observed in about 7 hours after i.m injection of 10mg/kg in human body. The peak value is about 0.8μg/ml within the plasma half-life of about13 hours. 1t is widely distributed in the body

with the highest level found in the brain and followed by the liver and kidney. It is mainly excreted in the feces with a part in urine.

6. Pharmaceutical particulars

6.1 List of excipients

None

6.2 Incompatibilities

Studies and reviews in the literature demonstrated that the active substance of Artemether had no interactions with other drugs on decreasing therapeutic effects and increasing toxicity and side effects in human bodies.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Preserve in well closed container, protected from light and stored in a cool place.

6.5 Nature and contents of container

Artemether injection is filled in the ampoules. Then, place the ampoules in the plastic trays. Finally, put plastic trays in the boxes.

6.6 Special precautions for disposal and other handling

Not applicable.

7. Marketing Authorization Holder

MAYDON PHARMACEUTICAL LTD.

Address: 15,Wilmer Street, Off Town, Planning Way, Ilupeju Lagos state, Nigeria

8. Marketing authorisation number(s)

9. Date of first authorisation/renewal of the authorisation

10. Date of revision of the text